## REMARKS

### Formal Matters

Claims 1 and 224-243 are pending after entry of the amendments set forth herein.

Claims 2-223 have been canceled, without prejudice to the possibility of filing one or more continuing applications directed to the subject matter recited therein.

Claims 234-243 have been newly presented.

Claims 1 and 224-234 were examined.

Claims 1 and 224-234 were rejected.

Applicants respectfully request reconsideration of the application in view of the amendments and remarks made herein.

No new matter has been added.

### The Office Action

### Claim Rejected Under 35 U.S.C. Section 102(e) (Boyd et al.) or, in the alternative, under 35 U.S.C. Section 103(a) (Boyd et al. in view of Ley)

Claims 1, 224, 226-228 and 230 were rejected under 35 U.S.C. Section 102(e) as being anticipated by Boyd et al., U.S. Patent No. 5,799,661 or, in the alternative, under 35 U.S.C. Section 103(a) as being obvious over Boyd et al. in view of Ley, U.S. Patent No. 5,514,076.

The Examiner asserted, inter alia, that Boyd et al. discloses a device in Figs. 42-44 that includes a flexible main body 238 having a contact surface and an elongated malleable member extending along a length of said flexible main body member (metal wire) (column 21, lines 25-45), and that the malleable member is capable of being shaped to engage the surface of the beating heart and is capable of being continuously adjustably shapeable by manipulation thereof to a desired shape and wherein upon release of manipulation forces, said malleable member maintains said desired shape and maintains a contact surface in the desired shape. The Examiner referenced column 19, lines 60-65 and column 21, lines 30-40 as supporting this position as the wire is made of nickel titanium alloy.

Applicants strongly traverse. It is respectfully submitted that Boyd et al. discloses at column 21,

lines 37-40, that the wire that the Examiner has interpreted as a "malleable member" is rather, a "resilient metal wire, such as spring temper stainless steel or a superelastic nickel/titanium alloy, or a composite of metal and plastic. Likewise, Boyd et al. column 19, lines 60-65 disclose that the wire is made of a highly resilient material such as a superelastic nickel/titanium alloy or a spring temper stainless steel or titanium alloy. Accordingly, it is respectfully submitted that although these materials are capable, as designed and used, of being shaped through manipulation into a desired shape, they are not capable of retaining said shape once the manipulation forces have been released. Quite the contrary, the materials are designed so that they do not retain the shape, this is a key design feature of a superelastic material or spring temper metal. While the limits of such materials can be exceeded, the limits are not exceeded when they are used as intended and designed for. Accordingly, it is respectfully submitted that the Examiner is being unreasonable in his interpretation of the reference, because it actually functions in the opposite manner that the Examiner is suggesting.

To still further clarify these distinctions, the independent claims have been amended above to recite that said malleable members are continuously adjustably shapeable by manipulation thereof to any one of a plurality of desired shapes, and wherein upon release of manipulation forces, said malleable member maintains said desired shape into which it was adjustably shaped and maintains said contact surface in said desired shape. It is respectfully submitted that the heat exchanger 231 of Boyd does not meet these recitations as amended, as it is resilient.

The Examiner asserted that Ley teaches a device that uses Nitinol in order to conform to the shape of an object. The Examiner asserted that it would have been obvious to modify the device of Boyd et al. to include the material of Ley, in order to allow the contact surface to better conform to the heart and thereby aid in stabilization.

Applicants respectfully traverse. It is respectfully submitted that Boyd et al. already describes use of the material disclosed by Ley, as Nitinol is merely a trade name for superelastic nickel/titanium alloy and this is disclosed by Boyd et al., e.g., see column 21, line 39. Accordingly, the combination of references suggested by the Examiner, in the manner suggested by the Examiner, would not change the Boyd et al. device at all. Furthermore, the superelastic nature of the metal, while allowing it to conform to a surface, is not capable of maintaining the conforming shape once the forces required to make it conform have been removed.

Still further, Applicants have amended the claims to recite a plurality of contact members, which are configured to be contacted to tissue on opposite sides of an anastomosis site. It is respectfully submitted that neither of the references teach or suggest these features.

In view of the above amendments and remarks, the Examiner is respectfully requested to reconsider and withdraw the rejection of claims 1, 224, 226-228 and 230 under 35 U.S.C. Section 102(e) as being anticipated by Boyd et al., U.S. Patent No. 5,799,661 or, in the alternative, under 35 U.S.C. Section 103(a) as being obvious over Boyd et al. in view of Ley, U.S. Patent No. 5,514,076, as being inappropriate.

**Claim Rejected Under 35 U.S.C. Section 103(a) (Boyd et al./Ley in view of Buckman, Jr. et al.)**

Claims 225 and 229 were rejected under 35 U.S.C. Section 103(a) as being unpatentable over Boyd et al., U.S. Patent No. 5,799,661/Ley, U.S. Patent No. 5,514,076, in view of Buckman, Jr. et al., U.S. Patent No. 5,582,580.

The Examiner asserted that Boyd et al./Ley disclose the invention substantially as claimed except for a device that includes a means for introducing positive/negative fluid pressure to the contact member.

Applicants respectfully traverse and submit that Boyd et al., as well as Boyd et al. in view of Ley, fails to disclose, teach or suggest a contact member that is variably shapeable to a plurality of different shapes as claimed, or elongated malleable members as claimed, or a having a shaft connectable to said contact members as claimed.

The Examiner asserted that Buckman, Jr. et al. teaches a contact member 82 that is malleable (Fig. 7, column 9, line 28-column 10, line 63) and that it would have been obvious to modify the device of Boyd et al. to include a means for introducing pressure to the contact member, as taught by Buckman, Jr. et al. in order to provide an alternate means of shaping the contact member that allows the contact member to have a plurality of different shapes.

Applicants respectfully traverse. It is respectfully submitted that Buckman, Jr. et al. does not disclose a malleable contact member 82, but rather that 82 is a heart contacting member having a flexible sidewall, see column 9, lines 46-48. Further, Buckman, Jr. et al. applies pressure to the contact member to apply a massaging motion to the heart. There would have been no need for this functionality in the hypothermia device 230 of Boyd et al. It is respectfully submitted that it would not have been obvious to modify Boyd et al. as suggested by the Examiner, as this would only overcomplicate (and add to the expense of ) the design of the heat exchanger, with little or no value or advantage to be gained therefrom.

Further, neither Boyd et al./Ley nor Buckman, Jr. et al., whether taken alone or in any proper combination, discloses, teaches or suggests a malleable member that is continuously adjustably shapeable by manipulation thereof to any one of a plurality of desired shapes, and wherein upon release of manipulation force, said malleable member maintains said desired shape. It is respectfully submitted that this claimed characteristic is the opposite of what is disclosed by Boyd et al., as the heat exchanger and backbone of Boyd et al. resiliently return to an unfolded position after manipulation thereof and release of manipulation forces. Likewise, the walls 84 of member 82 of Buckman, Jr. et al. are not malleable as claimed.

In view of the above amendments and remarks, the Examiner is respectfully requested to reconsider and withdraw the rejection of claims 225, 229 and 231-234 under 35 U.S.C. Section 103(a) as being unpatentable over Boyd et al., U.S. Patent No. 5,799,661/ Ley, U.S. Patent No. 5,514,076, in view of Buckman, Jr. et al., U.S. Patent No. 5,582,580, as being inappropriate.

**New Claims 235-234**

New claims 235-243 have been submitted above. Support for these claims can be found in claims 224-230 and throughout the specification and drawings. Applicants respectfully request the allowance of claims 235-243 in the next Official Action.

**Conclusion**

Applicants submit that all of the claims are in condition for allowance, which action is requested. If the Examiner finds that a telephone conference would expedite the prosecution of this application, please telephone the undersigned at the number provided.

The Commissioner is hereby authorized to charge any underpayment of fees associated with this communication, including any necessary fees for extensions of time, or credit any overpayment to Deposit Account No. 50-2653, order number GUID-005CON6.

Respectfully submitted,
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